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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,313	06/22/2001	Ian Tomlinson	8039/1122	9556

29933 7590 03/12/2003

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1639

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/888,313	TOMLINSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	My-Chau T. Tran	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 November 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 56-117 is/are pending in the application.
- 4a) Of the above claim(s) 69-77 and 87-117 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 56-68 and 78-86 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 June 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1639

**DETAILED ACTION**

1. Applicant's amendment filed 11/27/02 in Paper No. 8 is acknowledged and entered.

Claims 1-55 are canceled. Claims 56-117 are added. Claims 56-117 are pending.

***Election/Restrictions***

2. Applicant's election with traverse of Group I (Claims 1-8, 16-25, 34-36, 45-47, and 55) in Paper No. 7 is acknowledged. The traversal has been considered but is moot in view of applicant cancellation of claims 1-55.

3. It is noted that applicants have submitted the relationship of the newly filed claims (Claims 56-117) to the Groups set forth in the Restriction Requirement mailed on 11/1/02. This relationship of the newly filed claims (Claims 56-117) to the Groups set forth in the Restriction Requirement have been considered and acknowledged. The Groups are as follows for the newly filed claims:

- a. Group I: Claims 56-68 and 78-86
- b. Group II: Claims 76-86
- c. Group III: Claims 69-74, and 78-86
- d. Group IV: Claims 75-86
- e. Group VII: Claims 87-92
- f. Group VIII: Claims 93-99
- g. Group XVI: Claims 100-103
- h. Group XIX: Claims 104-110

Art Unit: 1639

i. Group XX: Claims 111-117

j. ***No analogous new claims for Groups V-VI, IX-XV, and XVII-XVIII.***

4. Applicant's election with traverse of Group I (Claims 56-68 and 78-86) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Group I, Group VII (Claims 87-92), and Group XVI (Claims 100-103) should be rejoined because there is no two-way distinctiveness between the claims of Group I, Group VII, and Group XVI and the search would not impose an undue burden.

This is not found persuasive because the methods of Group I, Group VII, and Group XVI are distinct from each other because they require different method steps for reasons of record. Further, for the different methods, the steps are different, requiring different reagents and/or producing different products/results. For example, in the case of detecting the interaction of two compounds such as compound A and compound B if compound A react with compound B a red signal is produce (the method of Group I). But if compound A does not react with compound B a green signal is produce (the method of Group VII). These two methods are distinct because different results are produced that is different signal is being detected. For example, the method of detecting the interaction of two compounds such as compound A and compound B (the method of Group I) id different from the method of detecting the interaction of compound A with compound A (the method of Group XVI). These two methods are distinct because different results are produced that is different reagents are use. Therefore, the methods of Group I, Group VII, and Group XVI are distinct from each other and the searches required are not co-extensive thus requiring a burdensome search.

Art Unit: 1639

The requirement is still deemed proper and is therefore made **FINAL**.

5. Claims 69-77 and 87-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.
6. Claims 56-68 and 78-86 are treated on the merit in this Office Action.

***Priority***

7. Acknowledgment is made of applicant's claim for foreign priority based on two applications filed in United Kingdom on 10/25/2000 and 6/23/2000. It is noted, however, that applicant has not filed a certified copy of both applications, which are 0026099.2 (10/25/00) and 0015443.5 (6/23/00), as required by 35 U.S.C. 119(b).

***Claim Objections***

8. Claims 78 and 86 are objected to as an improper dependent claim since it also depends on non-elected claims that result in a broken pendency chain.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1639

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 56-61 and 78-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of Gordon et al. (US Patent 5,486,452).

Buechler et al. disclosed a method of producing a multivalent polypeptide display library that can be used as diagnostic reagents (col. 2, lines 17-18; col. 4, lines 20-24). The polypeptides comprise of a heavy or light chain polypeptide of V<sub>H</sub> or V<sub>L</sub> sequences (col. 10, lines 53-65).

The method of Buechler et al. does not expressly disclose that the polypeptides are applied onto a solid support.

Gordon et al. disclose a method for immunological analysis consisting of a porous solid support containing an array of delimited adsorption areas of antigens, and/or immunoglobulins (col. 2, lines 10-16; col. 8, lines 33-44). The antigens or immunoglobulins are applied to the solid support by direct contact by which terms any mechanical transfer (col. 6, lines 6-18). The antigens or immunoglobulins can be applied so as to give any suitable geometry that is the formed adsorption areas being in the form such as dots, spots or lines.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polypeptides are applied onto a solid support as taught by Gordon et al. in the method of Buechler et al. One of ordinary skill in the art would have been motivated to include the polypeptides are applied onto a solid support in the method of Buechler et al. for the advantage of providing a device or system that simplify an immunoassay method and permit the establishment of a detailed “antibody profile” (Gordon: col. 1, lines 62-64). Since both Gordon et al. and Buechler et al. disclose an immunoassay method based on antigen- antibody detection (Gordon: col. 7, lines 33-62-66; Buechler: col. 8, lines 8-11).

12. Claims 56-66 and 78-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of Miller et al. (WO 99/39210).

Buechler et al. disclosed a method of producing a multivalent polypeptide display library that can be use as diagnostic reagents (col. 2, lines 17-18; col. 4, lines 20-24). The polypeptides comprise of a heavy or light chain polypeptide of V<sub>H</sub> or V<sub>L</sub> sequences (col. 10, lines 53-65).

The method of Buechler et al. does not expressly disclose that the polypeptides are applied onto a solid support.

Miller et al. disclose a method for determining the protein profile of a biological sample (pg. 5, lines 12-30 to pg. 6, lines 1-7). The method comprise of a primary array proteins wherein X<sub>n</sub> is the coordinate along a first dimension of the array and Y<sub>n</sub> is the coordinate along a second dimension of the array. Screening the primary array with a plurality of antibodies and preparing the secondary array of antibodies that bind specifically to the proteins of the primary array.

Art Unit: 1639

Determining the protein in the biological sample by screening the secondary array with the biological.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polypeptides are applied onto a solid support by Miller et al. in the method of Buechler et al. One of ordinary skill in the art would have been motivated to include the polypeptides are applied onto a solid support in the method of Buechler et al. for the advantage of providing a multiple array screening systems that could be readily applied to an entire proteomes (Miller: pg. 4, lines 21-23). Since both Miller et al. and Buechler et al. disclose an immunoassay method based on antigen-antibody detection using fusion protein (Miller: pg. 5, lines 12-30 to pg. 6, lines 1-7; pg. 20, lines 4-12; Buechler: col. 8, lines 8-11).

13. Claims 56-68 and 78-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of de Wildt et al. (*Nature biochemistry*, **2000**, 18(27):989-994).

Buechler et al. disclosed a method of producing a multivalent polypeptide display library that can be used as diagnostic reagents (col. 2, lines 17-18; col. 4, lines 20-24). The polypeptides comprise of a heavy or light chain polypeptide of V<sub>H</sub> or V<sub>L</sub> sequences (col. 10, lines 53-65).

The method of Buechler et al. does not expressly disclose that the polypeptides are applied onto a solid support.

De Wildt et al. disclose a method for screening antibody-antigen interactions, whereby many antibodies are screened in parallel against many antigens, and the filter-screening techniques is applied to the ordered arrays of antibodies generated by robotic picking and

Art Unit: 1639

gridding (pg. 989, lines 12-16). The method comprise of colonies of antibodies are picked into 384 well plates and grown (pg. 993, lines 21-47). The colonies are then gridded in a 4x4 pattern onto a large square plate covered with a nitrocellulose filter. A second filter is coated with the ligand protein L. The first filter containing the antibodies colonies is transferred onto the plate covered with the second filter and antibody binding to the second filter is detected.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polypeptides are applied onto a solid support as taught by De Wildt et al. in the method of Buechler et al. One of ordinary skill in the art would have been motivated to include the polypeptides are applied onto a solid support in the method of Buechler et al. for the advantage of providing a high-throughput screening of recombinant antibodies without "sticky" or cross-reactive colonies (De Wildt: abstract). Since both De Wildt et al. and Buechler et al. disclose an immunoassay method based on antigen-antibody detection ((De Wildt: pg. 989, lines 12-16; Buechler: col. 8, lines 8-11).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the

Art Unit: 1639

organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct  
March 10, 2003



PADMASHRI PONNALURI  
PRIMARY EXAMINER